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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/766,389 | 01/26/2004 | Stanton B. Gelvin | 3220/95461 | 3359 |

7590 09/19/2006

Alice O. Martin
Barnes & Thornburg
P.O. Box 2786
Chicago, IL 60690

EXAMINER

ZHENG, LI

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1638

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,389

Applicant(s)

GELVIN ET AL.

Examiner

Li Zheng

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3222004/6152006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. A U.S. Application serial number is recited on page 1, line 14 (see specification amendments filed on 1/26/2004). The status of the application should be updated. If the application was allowed, please insert the U.S. patent number.

2. The disclosure is objected to because of the following informalities:

Figures 1-3 contain multiple views that are labeled with a letter. However, the brief description of the figures in the specification does not recite those labels (page 4, lines 16-34). The brief description should be amended to recite those labels. See 37 CFR 1.74.

Appropriate correction is required.

3. The brief description of Figure 1B or the figure itself, must identify the sequences within the figures by their sequence identifiers. See 37 CFR 1.821.

Claim Objections

4. Claims 10 are objected to because of the following informalities: claim 10 has a typographic error. The recitation, "T-cell" should be replaced by --T-DNA--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4: the recitation, "one additional", render the claim indefinite. Does the recitation indicate that that the claimed plant is Arabidopsis? Does the plant have to comprise at least 2 copies of the gene? It is suggested to replace claim 4 with – A transgenic plant transformed with the RAT5 gene of Arabidopsis--.

In claim 11: the claim indicates that expression of the gene enhance plant transformation. Is the host cell limited to plant cells? If so, it is suggested that the claim be amended to indicate the cell is a plant cell.

6. Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of full content of the specification indicates that obtaining genes involved in T-DNA integration or genes capable of overexpressing histone to enhance plant transformation is essential to practice the invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

A review of the claims indicates that they are broadly drawn to a genus of genes involved in T-DNA integration or additionally capable of overexpressing histone to enhance plant transformation. However, neither the specification nor the prior art teaches a representative number of the species of the claimed genus except for the RAT5 gene itself. The conserved structures of those genes that correlate to the function, which is involved in T-DNA integration or also cause overexpression of

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histone, are not taught in the specification. The specification does not teach any features of the genes, such as regions coding for essential sequences of the RAT5 protein relevant to functionality. Without further guidance, it is concluded that the applicants do not have the possession of the claimed genus.

7. Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host plant expressing H2A histone protein, does not reasonably provide enablement for a host plant expressing any gene involved in T-DNA integration or also capable of overexpressing histone to enhance plant transformation, or non-plant host cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Claims 10-12 are broadly drawn to a host cells expressing any gene involved in T-DNA integration or also capable of overexpressing histone to enhance plant transformation or RAT5 gene.

The specification teaches that RAT5 gene of Arabidopsis, which complements a T-DNA tagged Arabidopsis mutant, rat5, that is deficient in T-DNA integration, encodes a histone H2A protein (page 6 line 32 to page 8 line 19 and also the paragraph bridging pages 9-10). Overexpression of RAT5 gene in wild type Arabidopsis plant improves the transformation efficiency (the paragraph bridging pages 8-9).

The specification only teaches that overexpression of RAT5 gene in wild type Arabidopsis plant improves the transformation efficiency. The prior art teaches two wheat histone H2A genes which may function in conformation changes in chromatin structure (Huh et al. 1997, Plant Mol. Biol. 33:791-802). However, a gene involved in T-DNA integration encompasses all genes from all sources in all pathways involved in T-DNA integration, many of which are not even identified in the art given the teaching of Gelvin (2000, Annu. Rev. Plant Physiol. Plant Mol. Biol. 51:223-256) that T-DNA integration is a very complicated and poorly understood process (page 235, the 1st paragraph). The claimed genes at least include genes involved in regulating expression of H2A genes, performing post-translational modification and degradation of H2A. None of those regulating processes is taught in the specification, or the genes involved in those pathways. Undue experimentation would be required for a person skilled in the art to identify all the pathways involved in T-DNA integration as well as genes in those pathways. The specification also does not teach any genes capable of overexpressing histone which also at least encompass transcriptional factors regulating the expression of histone genes. In addition, histone genes also encompass at least genes in H3, H4, H1, H2A and H2B subfamilies. Therefore, even if those regulating genes were known, not all histone genes from all sources are capable of enhancing plant transformation by overexpression. Undue experimentation would be required to determine which histone genes are able to enhance plant transformation and which regulating genes can cause overexpression of those histone genes. See *Genentech Inc. v. Novo Nordisk, A/S* (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that “the

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specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Finally, there is no evidence in the prior art or the specification that overexpression of histone H2A protein can improve T-DNA integration and transformation of non-plant host cells. Given the breath of the claims, lack of guidance on genes and pathways involved in T-DNA integration, histone genes capable of enhance plant transformation, as well as genes that cause overexpression of those histone genes, undue experimentation would have been required by one skilled in the art to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Regensburg-Tuink et al. (1993, Nature 363:69-71).

Regensburg et al. teach isolation of transgenic *N.glauca* plants in which the *virF* gene is expressed using CaMV 35S promoter. The *virF* gene causes increased susceptibility for tumor formation of such transgenic plants due to a more efficient T-DNA uptake (page 70, 3rd paragraph of right column). Given the broad interpretation of “gene involved in T-DNA integration”, the reference meets all the limitation set by claim 10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Please note that the instant claims 4 and 10-12 belong to one of the invention groups in original claim set of U.S. Patent Application No. 09/661,960, which became U.S. Patent No. 6,696,622, and were withdrawn from consideration due to the restriction requirement filed on April 18, 2002. Therefore, no double patenting rejection is made in this regard.

9. Claims 4, 10-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/098,161.

Claim 12 of copending Application No. 10,098,161 is drawn to a method for increasing the Agrobacterium transformation efficiency using a host plant expressing transgenically RAT5 of Arabidopsis encoding a H2A histone. Although the claims of copending Application No. 10/098,161 are not drawn to the transgenic plant but rather a method for increasing the Agrobacterium transformation efficiency, the claimed transgenic plants in instant claims are produced by the method. The property of being involved in T-DNA integration is inherent to the histone genes.

This is a provisional obviousness-type double patenting rejection.

10. Claims 4 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 , 13, and 24 of copending Application No. 10/664,658 ('658).

Claim 8 of copending Application No. 10,664,658 is drawn to a plant cell overexpressing the Arabidopsis RAT5 gene. As the co-pending claim does not limit the cell to being Arabidopsis, it is obvious that the RAT5 gene would have to have been transformed into non-Arabidopsis host cells to overexpress it, thereby giving the host one more copy than originally was present. Claim 13 of copending Application No. 10/664,658 is drawn to a method that produces a transgenic plant into which at least one copy of the Arabidopsis RAT5 gene was introduced. Claim 24 of copending Application No. 10/664,658 is drawn to any host cell transformed with any gene involved in T-cell integration and is capable of affecting overexpression of histone to enhance plant transformation frequency, and anticipates instant claim 10.

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This is a provisional obviousness-type double patenting rejection.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Claims 11 and 12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24 and 25 of copending Application No. 10/664,658. Claims 24 and 25 of copending Application No. 10/664,658 and instant claims 11 and 12 have the same scopes, respectively. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

Claims 4 and 10-12 are rejected.

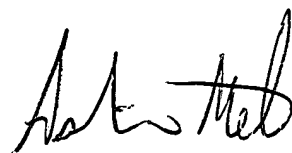
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

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The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', is positioned above the printed name.

**ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER**